Appendix A

PentaBDE Facts

Summary of USEPA's Understanding of PBDEs

Polybrominated diphenylethers (PBDEs) are members of a broader class of brominated chemicals used as flame retardants; these are called brominated flame retardants, or BFRs. There are commercial mixtures of PBDEs with different average amounts of bromination: penta-, octa-, and decaBDE. These chemicals are major components of commercial formulations often used as fire retardants in furniture foam (pentaBDE), plastics for TV cabinets, consumer electronics, wire insulation, backcoatings for draperies and upholstery (decaBDE) and plastics for personal computers and small appliances (octaBDE). The value of these chemicals is their ability to slow ignition and rate of fire growth, and as a result increase available escape time in the event of a fire involving the above consumer products.

Although use of these chemicals is intended to save lives and property, there have been unintended consequences. Environmental monitoring programs in Europe, Asia, North America, and the Arctic have detected several PBDEs in human breast milk, fish, aquatic birds and elsewhere in the environment. Tetra- to hexabrominated diphenyl ethers are the PBDEs most frequently detected in wildlife and humans. The exact mechanisms or pathways by which the PBDEs end up in the environment and humans are not known yet, but would include releases from manufacturing or processing of the chemicals into products like plastics or textiles, aging and wear of the end consumer products and direct exposure during use (e.g., from furniture).

EPA is not only interested in responding to monitoring data, however. The Agency continually looks for pollution prevention opportunities; the Pollution Prevention Act of 1990 and EPA's Pollution Prevention Strategy establish that pollution should be prevented or reduced at the source whenever feasible. The Agency has also made protection of children's health a fundamental goal of public health and environmental protection in the United States.

In general, the human health and environmental concerns are higher for the lower brominated mixtures (i.e., pentaBDE and octaBDE), and data suggest that higher brominated forms such as decaBDE can be altered to form more toxicologically active lower brominated forms. The limited toxicity test data that is currently available indicate the potential for adverse effects to humans and environmental organisms, especially for lower brominated mixtures, but existing hazard and exposure information on PBDEs is incomplete. More needs to be understood about the environmental fate and the exposure pathways that lead to PBDE presence in wildlife and people. PBDEs appear to be persistent and bioaccumulative in the environment. EPA believes an improved understanding of potential risks posed by the different PBDE mixtures in their various use applications is needed. EPA is addressing PBDE information needs with a three-pronged approach, which includes:

- Efforts to better understand the environmental properties, exposure pathways and how these chemicals are getting into human tissue;
- Research and detailed testing to determine health and environmental effects; and
- Evaluation of potential substitutes, which includes the analysis of technical performance, cost-effectiveness and risk-risk trade-offs related to fire prevention and toxicity.

EPA offices and regions are working with fire safety advocates, industry, environmental and public health groups, other federal agencies, state governments and other national governments to answer the key questions and provide a basis for informed risk reduction decisions, including potential regulatory and voluntary actions. In November 2003, Great Lakes Chemical Corp., the only U.S. manufacturer of pentaBDE and octaBDE, announced a voluntary phase out of both those chemicals by the end of 2004.

Toxicity

There are commercial mixtures of PBDEs with different average amounts of bromination: penta-, octa- and decaBDE. In general, the human health and environmental concerns are greater for the lower brominated mixtures.

Penta- and OctaBDE

Effects on induction of hepatic enzymes were the basis of the EPA Integrated Risk Information System (IRIS) assessments of commercial pentaBDE and octaBDE mixtures which were completed in 1990. However, although liver enzyme induction was used as the basis for the RfD then, based on current methodology, this endpoint would not now be used as the basis of an RfD given the absence of other negative liver effects or histopathology. An update of the IRIS assessment for PBDE's is in progress. Several recent studies in young laboratory animals (rats and mice) exposed to commercial pentaBDE or to several individual congeners during gestation have shown some evidence of alterations in several behavioral parameters, deficits in learning and memory, and delays in the onset of puberty. Prenatal exposure to octaBDE mixtures in laboratory animals has resulted in reductions in fetal body weight, and delays in ossification - a longer than normal period before hardening of the bones. PentaBDE and octaBDE mixtures and individual congeners have also been shown to disrupt normal thyroid hormone levels in adult rats and mice. This could have possible concerns for developmental neurotoxic effects since it is well-established that disruption of thyroid hormone levels in the pregnant female may affect brain development in the fetus. The National Toxicology Program (an interagency program consisting of relevant toxicology activities of the Centers for Disease Control, Food and Drug Administration and National Institutes of Health) plans to conduct both chronic and subchronic toxicity studies on the commercial pentaBDE mixture, as well as the individual congeners appearing in greatest concentration in the mixture.

DecaBDE

Less is known about the potential toxicity of decaBDE. However, in contrast to penta- and octaBDE, decaBDE is poorly absorbed which may limit its potential toxicity. Some studies have shown thyroid and liver toxicity. Prenatal developmental toxicity studies in animals have been equivocal. A recent study in mice has provided some evidence of behavioral alterations. The European Commission will be requiring a more complete developmental neurotoxicity study in rodents to help clarify the potential for decaBDE exposure to result in developmental neurotoxicity. In addition, exposure to very high doses of decaBDE has been shown to cause tumors in laboratory animals.

Exposure

PBDEs have been measured in breast milk, adipose tissue and blood serum from human populations in Sweden, Finland, Germany, Japan, Spain, Canada and the United States. PBDE concentrations have steadily increased over 20 years of monitoring conducted in Sweden and Germany. In Sweden, PBDE levels in breast milk had doubled every 5 years between 1972 and 1997, with a decreasing trend since 1997. North American data are limited and additional studies are ongoing to determine relative levels in breast milk and blood serum compared to those found in Europe. However, average levels as measured in 23 human adipose tissue samples and 32 serum samples from among California women and 50 breast milk samples from Canada were higher than PBDE levels measured in Sweden.

Limited monitoring studies have found PBDEs in air, water, sediment, biota and sewage sludge throughout North America. The highest concentrations are generally associated with locations near facilities manufacturing or processing PBDEs. Concentrations of PBDEs are higher in municipal sewage sludge than in other environmental media. Recently reported PBDE concentrations in the United States and Canada are greater than those reported in Europe and Asia.

Different congeners are found at different levels in environmental media and wildlife. Generally the highest measured concentrations are for the tetra (>50%), penta (20-30%), hexa (15-20%) and hepta and octa brominated (< 20%) congeners. Which congeners are found and their relative and absolute concentrations vary from site to site.

Questions and Answers on PBDEs

1. What are PBDEs?

Polybrominated diphenylethers (PBDEs) are members of a broader class of brominated chemicals used as flame retardants; these are called brominated flame retardants, or BFRs. There are three commercial mixtures of PBDEs with differing average amounts of bromination: penta-, octa-, and decaBDE.

2. What are PBDEs used for?

These chemicals are major components of commercial formulations often used as flame retardants in furniture foam (pentaBDE), plastics for TV cabinets, consumer electronics, wire insulation, and backcoatings for draperies and upholstery (decaBDE), and plastics for personal computers and small appliances (octaBDE). The benefit of these chemicals is their ability to slow ignition and rate of fire growth, and as a result increase available escape time in the event of a fire.

3. What are concerns associated with PBDEs?

Although use of flame retardants saves lives and property, there have been unintended consequences. There is growing evidence that PBDEs persist in the environment and accumulate in living organisms, as well as toxicological testing that indicates these chemicals may cause liver toxicity, thyroid toxicity, and neurodevelopmental toxicity. Environmental monitoring programs in Europe, Asia, North America, and the Arctic have found traces of several PBDEs in human breast milk, fish, aquatic birds, and elsewhere in the environment. Particular congeners , tetra- to hexabrominated diphenyl ethers, are the forms most frequently detected in wildlife and humans. The mechanisms or pathways through which PBDEs get into the environment and humans are not known yet, but could include releases from manufacturing or processing of the chemicals into products like plastics or textiles, aging and wear of the end consumer products, and direct exposure during use (e.g., from furniture).

4. What is the Agency doing to better understand the possible risks from exposure to PBDEs?

EPA is currently evaluating a risk assessment and data needs analysis on PBDEs that was developed by industry for the Voluntary Children's Chemical Evaluation Program (VCCEP). This assessment evaluates the potential risks to children and prospective parents from all potential exposure scenarios. EPA will be releasing its views of the assessment, including any further VCCEP data needs, in the next few months.

Directly or through grant mechanisms, EPA has been supporting research aimed at a range of topics related to PBDEs, including measuring PBDE levels in umbilical cord blood from newborn U.S. infants, mothers' blood, house dust, food, breast milk, and children; potential thyroid toxicity and developmental neurotoxicity; and the environmental fate of the PBDEs upon their release during production or after disposal of products that contain these chemicals.

EPA's Office of Research and Development, National Center for Environmental Assessment, is enhancing its Integrated Risk Information System (IRIS) database on the PBDEs. IRIS is a database of human health effects that may result from exposure to substances found in the

environment. The Agency developed IRIS to provide consistent information on chemical substances for use in risk assessments, decision-making and regulatory activities. The information in IRIS is intended for those without extensive training in toxicology, but with some knowledge of health sciences.

5. How does this action complement the decision by the sole US manufacturer to phase out production by December 31, 2004?

This action builds on the November 3, 2003, announcement by the Great Lakes Chemical Corporation, the only U.S. manufacturer of these chemicals, who agreed to voluntarily phase-out production by December 31, 2004. In 2003, EPA commended Great Lakes Chemical Corporation for taking this responsible action. EPA is concerned that manufacture or import could be reinstated in the future, and thus believes it is necessary to have the opportunity to evaluate any new manufacture or import associated with these chemicals.

6. Why are these chemical important and are there substitutes?

These chemicals provide a very important benefit because of their ability to save lives and property by slowing ignition and rate of fire growth, and therefore increase available escape time in the event of a fire. However, EPA also believes both the phase out and the Significant New Use rule will further spur the development of safer alternatives.

EPA has been working to ensure that following the phasing out of these two chemicals, acceptable alternatives are available to industry. Such alternatives would need to meet technological requirements of industry users, flame retardancy requirements in US standards, and present lower hazards than the chemicals for which they are substituting. To promote these goals and to explore the safety of alternative flame retardant chemicals, EPA has convened a group of stakeholders in its Furniture Flame Retardancy Partnership, including chemical manufacturers and users, the furniture industry, government agencies, and consumer groups, who will work together to evaluate possible alternatives to PentaBDE.

7. Should consumers discard any products that might contain PentaBDE or Octa?

No, the EPA does not believe that there is a need to remove or replace products that may contain these chemicals. EPA has not concluded that PBDEs pose an unreasonable risk to human health or the environment. However, due to growing concerns, EPA believes that the phase out and the regulatory action taken in this announcement are useful steps to minimize and ultimately help prevent further exposure to these chemicals.

8. What are PBDEs commonly used for?

The PBDEs are major components of commercial formulations often used as fire retardants in furniture foam, plastics for TV cabinets, consumer electronics, wire insulation, and back-coatings for draperies and upholstery, and plastics for personal computers and small appliances. These chemicals slow ignition and rate of fire growth, and, as a result, increase available escape time in the event of a fire involving the above consumer products.

9. How are people exposed to PBDEs?

PBDEs are not chemically bound to plastics, foam, fabrics, or other products in which they are used, making them more likely to leach out of these products. PBDEs may enter the air, water

and soil during their manufacture and use in consumer products. The primary route of human exposure is currently unclear.

10. What is the Agency doing to better understand the occurrence of PBDEs in the environment?

EPA is addressing PBDE information needs with a three-pronged approach which includes: 1) efforts to better understand the environmental properties, exposure pathways, and how these chemicals are getting into human tissue; 2) research and detailed testing to determine health and environmental effects from exposure to PBDEs; and 3) evaluation of potential PBDE substitutes, which includes the analysis of technical performance, cost-effectiveness, and risk-risk trade-offs related to fire prevention and toxicity.

11. What efforts are underway to discourage continued use of the PBDEs?

In November 2003, the Great Lakes Chemical Corporation announced a voluntary phase out of PentaBDE and OctaBDE by the end of 2004. Great Lakes is the only U.S. manufacturer of these PBDEs. To follow up on this voluntary action, EPA is working with chemical manufacturers and end users to facilitate an orderly transition to safer substitutes. The State of California has enacted a law banning use of PentaBDE and OctaBDE by January 2008 (recently changed to June 1, 2006) and other states (including Maine, Hawaii, Washington, and New York) are also considering or have passed similar legislation. In Europe, the European Union enacted a ban on PentaBDE and OctaBDE in all products which took effect on August 15, 2004.

EPA is also working with the fire safety advocates, chemical manufacturers, manufacturers of end products such as furniture or plastics for electronics, environmental and public health groups, other federal agencies, state governments, and other nations to answer key questions and help people make informed decisions based on risk. EPA is considering both regulatory and voluntary actions.